APR 1 7 2001

K010630

VI. 510(k) SUMMARY

Manufacturer Information:

Procera Sandvik AB
126 80 Stockholm
Sweden

Submitter's Name:

Martin Sterner
Procera Sandvik, Inc.
1872 McBride Avenue
Fair Lawn, NJ 07410
USA

Phone: 201 398-7412
Fax: 201 398-7435

Device Name:

Common Name:	Yttria.stabilized tetragonal zirconia powder
Classification Name:	872.6660-Porcelain Powder for Clinical Use
Product Code:	EIH
Class:	II
Panel:	Dental

Indications For Use:

Y-TZP Powder is the raw material used by Procera Sandvik to form a coping to which a porcelain veneer is applied to form a dental crown.

Description:

Y-TZP Powder, is the raw material that, when used in conjunction with computer-assisted design, computer-assisted machining, and sintered to full density, forms a dental coping.

Y-TZP powder is compacted against the model of the tooth and is sintered to full density under extreme temperature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 7 2001

Mr.Martin Sterner
Quality Manager
Procera Sandvik, Incorporated
1872 McBride Avenue
Fair Lawn, New Jersey 07410-2812

Re: K010630
Trade/Device Name: Y-TZP Powder and Procera Allzirkon
Regulation Number: 872.6660
Regulatory Class: II
Product Code: EIH
Dated: February 27, 2001
Received: March 2, 20001

Dear Mr. Sterner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucente /for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devcies
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010630

VIII. INDICATIONS FOR USE

510(k) Number (if known): K010630

Device Name Yttria.stabilized tetragonal zirconia powder

Indications for Use:

Yttria.stabilized tetragonal zirconia powder is the raw material used by Procera Sandvik to form a coping to which a porcelain veneering porcelain is applied to form a dental crown.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off) Pamela Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010630